

## Journal Club Eastern Virginia Medical School Therapy Article

Resident: John Schneider

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**CITATION:** Armstrong J et al., **Non-operative management of early, acute appendicitis in children: is it safe and effective?** *J Pediatr Surg.* 2014 May;49(5):782-5.

I. WHAT IS BEING STUDIED?	
1. Study Objective	“To determine if early, acute appendicitis in children can be safely and effectively managed with antibiotics alone.”
2. Study Design	Retrospective case controlled review. Single surgeon Children’s Hospital, Ontario
3. Inclusion Criteria	A “classic presentation of appendicitis”, less than 48hrs of symptoms, and diagnosis of acute appendicitis confirmed on imaging
4. Exclusion Criteria	Signs of hemodynamic compromise; abscess or phlegmon on imaging
5. Interventions Compared	Non-operative management (NOM) with antibiotics alone vs operative management (OM) with appendectomy  ABX included “ IV ciprofloxacin and metronidazole or ampicillin, gentamicin, and metronidazole while hospitalized, followed by oral amoxicillin/clavulanate following discharge for a total of 7 days of antibiotics or NOM a single dose of preoperative antibiotics prior to laparoscopic appendectomy
6. Outcomes Evaluated	1: Primary – Failure of initial treatment or complications of treatment For NOM = worsening or non-resolution of symptoms or perforation For OM = peritonitis requiring reoperation

	<p>or surgical site infection.</p> <p>2. Secondary: Length of stay, recurrences, and repeat visits to the hospital with symptoms.</p>
<b>II. Are the results of the study valid</b>	
1. Was the assignment of patients randomized?	No. Retrospective study. Single physician study who offered “ non-operative management to all patients diagnosed with early, uncomplicated acute appendicitis. “
2. Was randomization concealed (blinded)?	N/A
3. Were patients analyzed in the groups to which they were randomized?	Yes. Patients were analyzed in their respective groups. So, failed NOM were still assessed as NOM. This is consistent with intention-to-treat analyses.
4. Were patients in the treatment and control groups similar with respect to known prognostic factors?	Yes. Demographics, time of symptom onset, labs all similar.
<b>III. Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?</b>	
1. Were patients aware of group allocation?	Yes. As a retrospective study, unlikely of bias on part of patients
2. Were clinicians aware of group allocation?	Yes. Which could lead to some element of performance bias. For example, those in the NOM group are d/c'd a bit earlier.
3. Were outcome assessors aware of group allocation?	Yes. Outcomes were pretty non-subjective i.e. need for appendectomy.
4. Was follow-up complete?	Yes, although NOM group was followed for 6.5 months and OM for 6 months
<b>IV. What were the results?</b> Answer the questions posed below	
1. How large was the treatment effect? (Difference between treatment and control group).	Two of 12 NOM patients (16.7% p=0.58) failed initial management. One required OM within 24 hrs. and the other at 6

	<p>weeks. So, total of 3 of 12 patients or 25% in NOM group required OM</p> <p>Groups were similar with respect to all primary and secondary outcomes. None with p value &lt;0.05 No CI's were reported. However, in table 3 they listed several p values as N/A which was not explained. .</p>
2. What was the estimated treatment effect at a 95% confidence interval? (Precision)	Not stated.
<b>V. Will the results help me in caring for my patients? (Applicable?)</b>	
1. Were the study patients similar to my patient?	Yes, we frequently see patients of this age group presenting with acute appendicitis
2. Were all clinically important outcomes considered?	No. , for the most part I think the authors did a good job an appropriate primary outcome Additional secondary “patient-centered” outcomes such as school or parental days work missed, costs, pain, return to normal activities were not measured.
3. Are the likely treatment benefits worth the potential harm and costs?	Unclear from this study as the numbers were quite small. However, for the most part the outcomes were similar between the two groups, so it appears that it may be safe and effective to trial non-operative management in some patients.

**Study Limitations:**

- Small sample size so not powered to reach statistical significance
- Short follow-up period and poorly described
- Retrospective review may have missed non-charted complications.
- Selection and performance bias as this was a single clinicians practice
- Did not define what constitutes “failure to improve”?

**Clinical Bottom Line:** Although the number of patients in this study was quite small, it does appear that in some patients, non-operative management of patients may be safe and effective and avoid exposing patients to the risks of surgery.